

REMARKS

1. Status of claims

Claims 12-14 are pending.

2. Information Disclosure Statement

The Examiner indicated that previously submitted references were not listed on a form PTO-1449 and were therefore not considered. An Information Disclosure Statement and PTO-1449 listing the previously submitted references is mailed concurrently herewith.

3. Objection to the specification

The Examiner objected to the specification for reciting, at p. 8, line 30, "mineral medium" instead of "minimal medium." By the above amendment, the term in question has been corrected. Applicants submit the basis for this rejection has been removed.

4. Claim rejections under 35 U.S.C. §112

The Examiner rejected claims 12-14 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner alleged that the specification did not reasonably convey to the skilled artisan that the inventors had possession of the claimed invention, specifically relating to L-galactose dehydrogenase (LGDH) having at least about 90% similarity or identity with SEQ ID NO:11 or coding regions encoding LGDH and having at least about 90% identity with SEQ ID NO:12. Applicants traverse this rejection.

The methodology for determining compliance with the written description requirement is given at MPEP 2163.II.A *ff*. First, what each claim as a whole covers is to be determined.

Second, the entire application is to be reviewed to understand how it provides support for the claimed invention and each element or step thereof. Third, whether there is sufficient written description to inform the skilled artisan that the applicant was in possession of the claimed invention as a whole at the time the application was filed is to be determined. In the present situation, the claims in question are original claims (identical to those originally presented in the parent application) drawn to a genus.

L-galactose dehydrogenase (LGDH) enzyme is described at p. 6, lines 4-9 and Figure 1. The skilled artisan would also have been aware of references known in the art at the time of filing of the parent application, such as Smirnov et al., WO 99/33995 and Smirnov et al., *Curr. Opin. Plant Biology* (June 2000). From these, it is clear that the functional term “LGDH” refers to NAD⁺-dependent enzymes capable of catalyzing the conversion of L-galactose to L-galactono-1,4-lactone. “Similarity” and “identity” are also well known terms to the skilled artisan, especially in view of description of the CLUSTAL program at pp. 13-14. The plain meaning of “at least about 90%” is apparent.

Applicants will now consider of the Examiner’s performance of the third step of the methodology. One way in which an adequate written description may be shown is by structural chemical formulae. Another way is by any description of sufficient, relevant, identifying characteristics. Applicants have shown an adequate written description in both ways.

The phrases “at least about 90% similarity to SEQ ID NO:XX” or “at least about 90% identity to SEQ ID NO:XX” are exactly equivalent to a list of sequences (with the ordinary skilled artisan understanding an amino acid or nucleic acid sequence as a “structural chemical formula”) differing from SEQ ID NO:XX by 0 amino acids/nucleic acids, 1 amino acids/nucleic acids (of which there are n such sequences, wherein n is the length of the sequence of SEQ ID

NO:XX), 2 amino acids/nucleic acids (of which there are $n^*(n-1)$ such sequences, wherein n is the length of the sequence of SEQ ID NO:XX), ... to about 10% * n amino acids/nucleic acids (of which there is a vast number of sequences for values of n common for the entire amino acid sequence of proteins). The phrases “at least about 90% similarity to SEQ ID NO:XX” or “at least about 90% identity to SEQ ID NO:XX”, being vastly more concise while providing equivalent information, are used solely as a convenience for the ordinary skilled artisan reading the description and claims.

Concerning a description of sufficient, relevant, identifying characteristics, these characteristics are given by *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 63 USPQ2d 1609 (Fed. Cir. 2002) as complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination thereof. The present claims recite LGDHs, which the skilled artisan would understand refers to enzymes having the functional characteristics of being NAD^+ -dependent and capable of catalyzing the conversion of L-galactose to L-galactono-1,4-lactone. These functional characteristics are coupled to a disclosed correlation between function and structure, namely, the levels of similarity or identity to SEQ ID NO:11 or 12 recited by the claims. The claims do *not* recite that every protein having at least about 90% similarity or at least about 90% identity to SEQ ID NO:11 or being encoded by a coding region having at least about 90% identity with SEQ ID NO:12 is an LGDH, i.e., has the functional characteristics discussed above. Rather, the claims recite proteins having both the functional characteristics of LGDH and a structure having at least about 90% similarity or at least about 90% identity to SEQ ID NO:11 or being encoded by a coding region having a structure having at least about 90% identity with SEQ ID NO:12.

Claims drawn to a genus require a written description of a “representative number of species.” There is no *per se* rule regarding how many species constitute a representative number. From *In re Herschler*, 591 F.2d 693, 200 USPQ 711 (CCPA 1979), it is clear that a genus “must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that [genus].” In view of *Herschler*, there is no need for a written description more specific than that required to lead the ordinary skilled artisan to the genus as a whole. The genera of the present claims are LGDHs having at least about 90% similarity or at least about 90% identity to SEQ ID NO:11 or being encoded by coding regions having at least about 90% identity to SEQ ID NO:12. Two specific species are presented: an LGDH having 100% identity to SEQ ID NO:11 and a coding region having 100% identity to SEQ ID NO:12. Turning to the protein, the species is not *a protein* having at least about 90% similarity or at least about 90% identity to SEQ ID NO:11, but rather *an LGDH* having at least about 90% similarity or at least about 90% identity to SEQ ID NO:11. Analogous reasoning holds for the species and genus of coding regions.

For at least these reasons, an adequate written description is provided, and Applicants request this rejection of claims 12-14 be withdrawn.

5. *Claim rejections under obviousness-type double patenting*

The Examiner provisionally rejected claims 12-14 under the judicially created doctrine of obviousness-type double patenting for allegedly being not patentably distinct over claims 7 and 11-14 of copending U.S. Pat. Appl. 10/606,302. Applicants request deferring substantive response to this rejection (such as the filing of a terminal disclaimer) until such time as claims are allowed in either the present case or U.S. Pat. Appl. 10/606,302.

6. *Claim rejections under 35 U.S.C. § 103*

The Examiner rejected claims 12-13 under 35 U.S.C. § 103(a) as being unpatentable over Berry *et al.*, US2002/0012979A1, (“Berry”), in view of Obermaier *et al.*, EMBL/GenBank/DDBT Entry O81884 (“Obermaier”). Specifically, the Examiner alleges Berry teaches a method that differs from the present claims by not teaching use of an LGDH having SEQ ID NO:11, but that Obermaier teaches an LGDH having SEQ ID NO:11 and that it would have been obvious for the skilled artisan to apply the LGDH of Obermaier to the method of Berry at the time the present invention was made. Applicants traverse this rejection.

The sequence reported by Obermaier was accessed by the undersigned on February 8, 2006 at <http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?val=75220139>. O81884 is the locus to which the sequence is assigned. The sequence is labeled “Hypothetical Protein... (L-Galactose Dehydrogenase)” and was assembled from seven submissions to GenBank, ranging from September 1998 to 2002. The only submission to indicate the hypothetical protein was LGDH was Gatzek *et al.*, *Plant J.* 30:541-553 (2002). The date of this submission is after the priority date of the present application. Further, Obermaier reports “On Sep 14, 2005 this sequence version replaced gi:7447943” (<http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?val=7447943>), accessed by the undersigned on February 8, 2006. A copy of GenBank 7447943 is attached for the Examiner’s convenience. GenBank 7447943 provides no evidence that any of its submitters identified the sequence as an LGDH. Therefore, the skilled artisan would not have recognized the sequence as an LGDH prior to the priority date of the present application.

Because the skilled artisan would not have recognized Obermaier as teaching an LGDH, there would exist no motivation to use the sequence of Obermaier in Berry’s method of

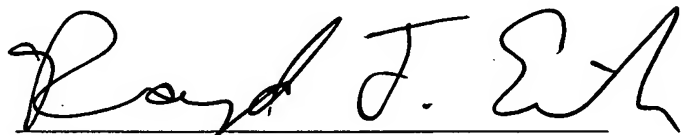
preparing ascorbic acid by use of an LGDH. Therefore, the references cannot properly be combined and Applicants request this rejection of claims 12-13 be withdrawn.

7. *Conclusion*

Applicants submit all pending claims are in condition for allowance except for resolution of the provisional double patenting rejection discussed above. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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